ENGN2225 Individual Design Portfolio

Medical Wearables: Vital Signs Monitoring for Patients

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Abstract

This portfolio explores the currently lacking use of wireless monitoring systems amongst patients in order to improve treatment outcomes and patient quality of life. It includes a formal problem definition, the proposed solution, and then a detailed systems engineering process. This explores the system scope, the design requirements and attributes, the proposed system's logic, functions and subsystems, as well as some research and recommendations into build materials and proposed product testing.

Table of Contents

Problem Statement **1**

The problem is introduced, explaining in detail what the problem is and why it needs to be solved.

The Solution **1**

The proposed solution to the problem is presented with explanation as to how it solves the problem and some conceptual sketches.

The details of the solution process are contained in the remaining sections of the portfolio.

1.0 System Scope **2**

The details of the process begin by setting some boundaries for the problem and the early stages of the solution definition. Within this, a small patient survey and some customer requirements are outlined, as well as a pairwise comparison of the requirements. The requirements include the functional input output requirements (most important) and user requirements such as comfort.

2.0 Design Attributes, TPMS & Analysis **4**

The customer requirements are translated into design requirements with performance measures and metrics. House of Quality analysis indicates strong relationships between the inputs and outputs of the device and a number of other features, indicating functionality should be pursued ultimately.

3.0 System Logic & Function Definition **7**

Concept generation leads to a chosen concept. Functional flows are defined for two scenarios.

4.0 Subsystem Definitions & Integration **9**

The different subsystems are defined and a diagram is generated to define their interactions. The design attributes are then assigned to these subsystems. Research is done on wireless adhesive patches, the user interface and wireless communications types.

5.0 Lifecycle Analysis **13**

The proposed materials, production factors, use life and product retirement are explored and defined.

6.0 Testing **14**

Some tests are proposed in order to verify the solution meets the design requirements. These are defined with specifics, the metrics they are measuring and the success requirements.

Conclusion & Next Steps **15**

Brief conclusion and mission statement as to the further development of this project.

Introduction

With healthcare costs around the world steadily rising (*Ferro 2012),* medical procedures, hospital stays and GP visits continue to become more streamlined than ever (*EMBS 2015).* Patients are sent home sicker, people living with chronic debilitating diseases are forced to personally manage their symptoms and the need for an intelligent health monitoring system for these people grows daily. The applications of computing are expanding and miniaturization of computer chips has not only made them more portable, but increasingly more efficient and powerful, and these characteristics could significantly impact the lives of these patients, as well as revolutionize the entire health care system. Wearable health technology is not a new concept, however, its uses do not currently meet the needs of health system. It is essential for recent computational developments to be applied to existing health monitoring systems to make them more efficient and portable, relieving the current pressure on the health system, and drastically improving the quality of life for patients.

Problem Statement

Current medical wearables present several downfalls; ranging from bulky and restrictive devices, to weak consumable goods that provide little to no vitally useful information. Somewhere in the middle lies the missing link. A device that combines the recent technological advances into a powerful system that can monitor the health of patients, providing useful information for the wearer and their doctors, powerful and intelligent analysis of the data, and a user friendly physical design that is un-restrictive and allows patients to live the fullest and healthiest life possible.

Outcomes in any process cannot be improved unless they are actively measured. To alleviate the stresses of rising healthcare costs on both doctors and patients, a system needs to be developed to utilize the latest in wireless biomedical sensory technologies in a user friendly way that can read, analyze and communicate the vital health indicators of individuals such that better decisions can be made to improve quality of treatment and life. Measuring these vital signs gives evidence of state of the body's function in a way that can give these insights. (*James 2015*)

Recent studies and advances in biomedical technologies show that the technology required for wireless monitors and sensors are already available, however, a system is required to take input from a large variety of these sensors, which collects and processes the information in a useful and non-restrictive way. *(Iran Daily 2012)*

The Solution

The solution provided is in the form of a wrist band with a small touch screen display that can connect to small wireless adhesive patches via Bluetooth. In addition to this, the wrist band can come with several sensors pre-installed in the inner edge of the band, ranging from heart rate monitors to pulse oximeters, providing a wire-free patient vital signs monitoring system. The band has a firm outer chassis that can come in a variety of colors, with a soft and comfortable inner surface made of silicone that can likewise come in a variety of colors. This system has not only examined the requirements of measuring and recording the data, but also looked into the needs of the patients; a comfortable, easy to use device that works around the patient's life, and not the other way around. This device has the potential to not only reshape general patient treatment, but the emergency department triage system, paramedic emergency situations and even military soldier health monitoring.

Figure 1 shows a concept sketch of the device, highlighting touch screen, the chassis made of two different plastics and the sensors found on the inside edge of the device. It is designed to be comfortable and fashionable whilst providing the essential functions required for vital signs monitoring.

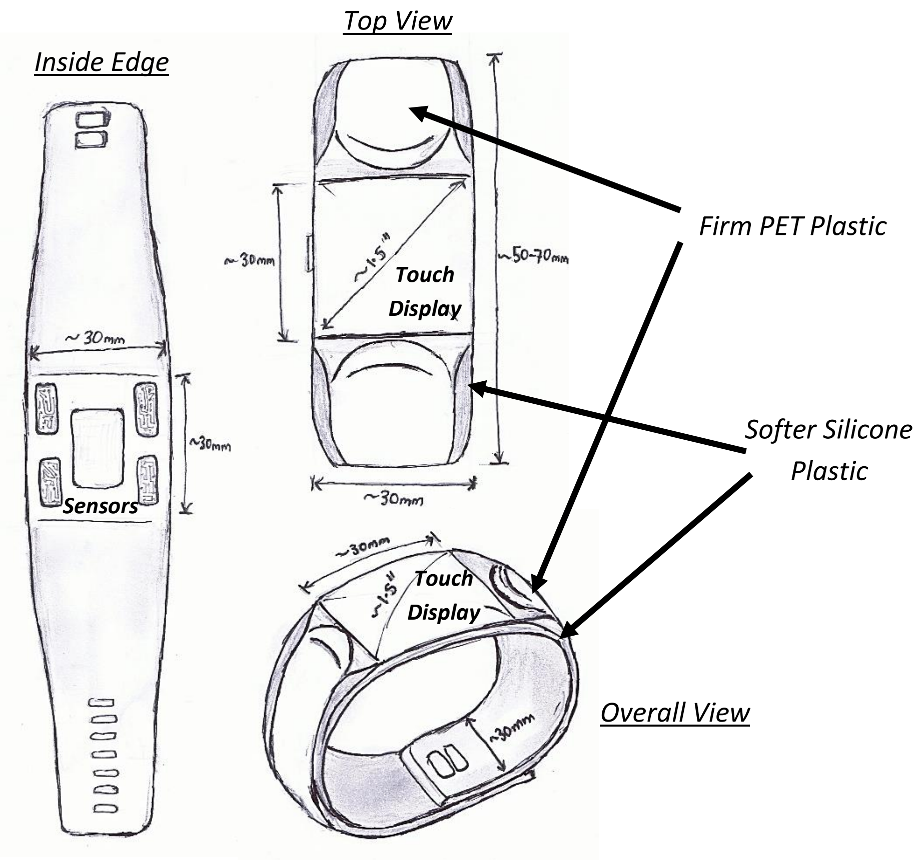

Figure 1: Concept sketches of the proposed solution

This portfolio outlines the process by which this system was defined, analyzed and solved with evidence for design decisions and selected attributes.

1.0 System Scope

To correctly consider the necessary aspects of the problem and correctly aim the design process, a definition of the system boundary is required. These boundaries help reduce complexity and contain the focus to a manageable size, clarifying necessary system outcomes and ensuring customer needs are most effectively met.

1.1 Defining the System Boundaries

The system boundaries outlined in *Table 1* have been defined by identifying and categorizing the factors affecting the system and the parts involved. These can be categorized by the parts of the system that can be controlled (Endogenous), outside factors that directly affect the system but cannot be controlled (Exogenous) and factors that won't be considered and therefore do not significantly affect the system at all (Excluded).

Table 1: System Boundary Definition

Endogenous	**Exogenous**	**Excluded**
Cost Materials Comfort Aesthetics Size Battery Life Sensors	Patient Size Patient Conditions/Health Power Sources Available Software/Computing	Public Consumers Gender Age Weather/Climate

Table 1 highlights that the scope of the problem has been narrowed purely to a medical application, therefore the solution is aimed at patients requiring medical health monitoring. Within this, the endogenous factors are those that are going to be defined by the system created to solve this problem. The exogenous factors, however, show that consideration of the patients and doctors eventually using the system must be considered in addition to those directly defined by the system. Public consumable goods have been excluded, as well as gender, age and locational effects.

If the implementation of the system in a purely medical setting proved successful, the scope of the system boundaries could be adjusted to consider more factors and the possibility of implementing a society-wide public good based around this concept. This would add great complexity and has therefore been excluded from consideration in this system in its initial design process.

1.2 The Customer Requirements

Customer requirements are essential to an effective product or system, and as outlined in the problem statement, a disconnection between the current needs of the medical system, its patients and doctors and the already available medical wearable devices is apparent. To gain greater perspective and insight of patient needs in this system, three users of medical wearable technologies were interviewed. They were asked to comment on their experience with these devices and how it impacted their lives.

The first two patients interviewed had experienced issues with heart functions and were subsequently prescribed a test period using an ECG monitor (Electrocardiogram to measure the electrical activity of their heart). Both of these patients emphasized the difficulty they experienced with the device as the wires and the size of the device restricted their normal daily activities. It was uncomfortable, bulky, unpleasant to look at and very limiting. Whilst the device served its purpose and measured the necessary data, it forced the patients to bend their lives around the device.

The third interviewee was a person with Type 2 Diabetes, who had recently moved from self-administered insulin injections, to a medical wearable device known as an insulin pump. The patient emphasized that his life had been dramatically and positively changed, making the effects of this disease on daily life barely noticeable. The device was capable of monitoring his blood sugars and administering doses of insulin far more accurately and regularly than a human ever could, constantly keeping his blood sugars within an ideal and normal range. The pump was durable, easy to use, blended in with normal life, and more importantly monitored and helped manage the effects the disease on his life. The outcomes of his treatment were vastly improved by measuring data that aided in decisions and management of the effects of diabetes.

1.3 Customer Requirements List

In consideration of the interviews performed with these patients, a number of requirements for this system are apparent and are seen in *Table 2* below.

Table 2: Design Requirements

Durable	The product must be able to be worn by the user in a large range of circumstances and environments, withstanding any normal daily activity.
Aesthetics	The product must be something people can wear confidently in their everyday life, having it blend in with other clothing items.
Cost	The product must be appropriately priced as a medical device, possibly receiving prosthetic status.
Comfortable	It must be comfortable and easy to wear.
Easy to Use	Special understanding must not be required for the product to fully aid daily life and treatment.

Inputs/Outputs	It needs to provide basic necessary information to the user, yet be capable of providing more detailed statistics for health professionals to monitor. It must have useful input options for users to note any necessary information. The measuring of information needs to be seamless and wirelessly received, transmitted and communicated to patients and health care professionals. The device must be modular, taking input from a variety of input sensory and monitor transmitters, also allowing the input transmitters to be catered for different patients. The device must display clinical usefulness, primarily have a clinical endpoint, providing data that can be measured objectively to aid in intervention and health decisions.

Table 2 highlights the main features mentioned by the interviewed patients, mainly outlining necessary functionality and user features that have made or may have made the experience better. More specifically, these customer requirements specify the technological features required in its inputs, outputs and clinical usefulness (which are a must) (*Papanek 2015*), however, still considering the necessary user features that would ensure the system is shaped to supporting the needs and lifestyle of the users. These user focused design requirements are highlighted by comfort, durability, aesthetics, ease of use and cost.

1.4 Requirements Analysis

Ranking the customer requirements provides insight into the features that are the most important, and allowing decision making and tradeoffs to be made systematically and with justification. *(Dym et al 2009)*

Table 3: Pairwise Comparison

	A	B	C	D	E	F	Sum	Rank
Durable (A)		1	1	0	1	0	3	3
Aesthetic/Fashionable Design (B)	0		0	0	0	0	0	6
Cost (C)	0	1		0	0	0	1	5
Comfortable (D)	1	1	1		1	0	4	2
Easy to Use (E)	0	1	1	0		0	2	4
Inputs/Outputs (F)	1	1	1	1	1		5	1

Table 3 outlines the relative importance of the customer requirements. Whilst all design requirements are important, they must be ranked such that necessary design decisions may be made throughout the design process. As previously highlighted, these customer requirements can be categorized by either the devices function, or its physical build and interface. The inputs and outputs (device's primary functions) have been identified as the most important of all the requirements, as the product is useless unless it basic functionality can cause any improvement patient quality of life and treatment. After this, user lifestyle features (physical build and interface) are ranked by importance, showing that whilst they all are important to the design, the comfort and durability of the design take precedence over its ease of use, looks and cost if/when design decisions take place. All customer requirements are aimed to be met.

2.0 Design Attributes, TPMS & Analysis

Analysis of the customer requirements is logically proceeded by a translation of these requirements into design requirements and appropriate, measurable performance measures. Table 4 shows these translations and they are marked with an intended direction for increase (+), decrease (-) and optimize (•).

Table 4: List of All Customer Requirements, Associated Design Requirements/Attributes and Measures

Customer Requirement	**ID**	**Design Requirement/Attribute**	**TPM**	**Metric**
Durability	DR01-01	Waterproof	+ Water and Dust resistance Rating	IPxx Rating
	DR01-02	Tough	+ Impact Resistance	IPK Rating
	DR01-03	Long Product Life	+ Material Life	Years
			+ MTBF	Years
Aesthetics	DR02-01	Multiple Customization Options	+ Color Options	#
			+ Design Options	#
Comfort	DR03-01	Wear-ability	+ Size Adjustability	Binary
			• Dimensions	cm
			- Weight	g
Ease of Use	DR04-01	Customer Input Options	+ User Inputs	#
	DR04-02	Software Integration and Compatibility	+ Number of platform compatibilities	#
Cost	DR05-01	Appropriate Cost	- Overall Cost	$
Inputs/Outputs	DR06-01	Measures Vital Signs	+ Sensor Measurement Accuracy	%
			+ Sensor Variety/Types	#
	DR06-02	Good Battery Life	+ Battery Capacity	mA/hr
			+ Battery Lifespan	Years
	DR06-03	Seamless Wireless Communications	• Type of wireless communications	Hz Range
			• Range of Wireless	m
			+ Number of devices and sensors	#
			• Server/Cloud updates	Binary
	DR06-04	Processes and analyses measured data	+ Processing Speed	Hz
			+ Accuracy of Analysis Techniques	%
			• Data Output Options	#

Table 4 provides a basis for the fundamental features of the system. Correct definition of design requirements that meet customer needs early in the design process provide confidence to move forward with a set of target functional/design requirements. A majority of the design requirements have increasing or optimized target markers, cost and weight excepted. For example, the range of the wireless communications will require optimization such that battery life is conserved, however normal use is not restricted to a certain range. Likewise the type of communications used by the system must be selected to suit the needs of the system and be based on an understanding of the impact and relationship each requirement has on the other. This requires a House of Quality analysis to determine the relationships between the most important features of the system.

2.1 House of Quality Analysis

To reduce complexity, only the top 4 customer requirements and associated design requirements are analyzed, as it can be argued that both aesthetic design features and cost are not only of lower importance, but can be more flexibly adjusted to work around the functional features of the product. (*Blanchard et al 2011)*

Table 5 outlines the house of quality analysis for this system, and in addition provides a correlation analysis in the pyramid structure above it. Comparing the design attributes to the design requirements, it becomes clear again that the higher importance design aspects show strong relationship to a large number of design attributes, for example, the 'Processes/Analyses Data' and 'Seamless Wireless Communications' appear to link to a large number of other attributes. This indicates that these main functional features are likely be the overall defining features of the design, which must come first. Any lower importance feature may experience trade-offs throughout the system design as a result of the assigned importance and associated relationships.

When considering the 'roof' of the HoQ, we see again some incidence and interaction between attributes of the systems main functional features, such as '*Sensor Variety & Types*' having a positive correlation with '*Analysis accuracy*'.

The house of quality analysis indicates further that ultimately the functionality should be pursued, despite any impacts it may have on other requirements such as comfort and durability. These statements are made cautiously however, as these other requirements are also important. Yet, within reason, leeway that must allowed such that the functionalities are met before user experience features.

Table 5: HoQ Analysis & MODIFIED Correlation Analysis

Correlation Legend:
+ Positive
- Negative
No Correlation

HoQ Legend:
9 = Strong Relationship.
3 = Moderate Relationship.
1 = Weak Relationship

Correlation Analysis														
Water & Dust Resistance	▨													
Impact Resistance		▨												
MTBF	+	+	▨											
Dimensions		-		▨										
User Inputs	-				▨									
Platform Compatibilities						▨								
Sensor Accuracy							▨							
Sensor Variety/Types								▨						
Battery Capacity				+			-	-	▨					
Battery Life			+							▨				
Range of Wireless	-								-		▨			
# Sensors/Devices						-		+	-		-	▨		
Processing Speed							-	-	-			-	▨	
Analysis Accuracy							+	+				+	-	▨

Relative Importance	**ID**	**Design Attributes** / **Design Requirements**	*Water & Dust Resistance*	*Impact Resistance*	*MTBF*	*Dimensions*	*User Inputs*	*Platform Compatibilities*	*Sensor Accuracy*	*Sensor Variety/Types*	*Battery Capacity*	*Battery Life*	*Range of Wireless*	*Number of Sensors/Devices*	*Processing Speed*	*Analysis Accuracy*
6	DR01-01	*Waterproof*	**9**		**9**		**3**		**1**							
7	DR01-02	*Tough*	**9**	**9**	**9**	**3**										
8	DR01-03	*Long Product Life*	**9**	**9**	**9**			**3**			**3**	**9**			**3**	
5	DR03-01	*Wear-ability*	**3**	**3**		**9**										
10	DR04-01	*Customer Input Options*					**9**	**3**								
9	DR04-02	*Integration/Compatibility*								**3**			**3**	**9**	**9**	
1	DR06-01	*Measures Vital Signs*					**3**		**9**	**9**	**3**		**1**	**9**	**9**	**9**
3	DR06-02	*Good Battery Life*			**3**						**9**	**9**	**9**	**9**	**9**	**3**
4	DR06-03	*Seamless Wireless Comm*						**9**	**3**	**3**			**9**	**9**	**9**	
2	DR06-04	*Processes/Analyses Data*			**1**		**3**	**9**	**9**	**9**	**9**		**9**	**9**	**9**	**9**
		TPM	*IPxx*	*IPK*	*yrs*	*cm*	*#*	*#*	*%*	*#*	*mA/hr*	*yrs*	*m*	*#*	*Hz*	*%*

3.0 System Logic & Function Definition

Once the specifics of the system have been identified through requirements definition and analysis, concepts to meet the requirements may be generated. *Table 6* shows concepts and ideas for each design requirement.

Table 6: Concepts generation table, showing specific ideas for each design requirement

Customer Requirement	**Design Requirement/Attribute**	**Concepts**
Durability	Waterproof	Quality build and materials with minimal number of crevices
	Tough	Strong, shock absorbent materials such as rubber/plastics.
Aesthetics	Multiple Customization Options	Simple, pleasing design that is easily manufactured with design options such as different colors, shapes or patterns.
Comfort	Wear-ability	Ergonomic design with low impact materials in contact with the user. Must be appropriately sized, not too big, not too small.
Ease of Use	Customer Input Options	An appropriate, simple user interface, minimal buttons.
	Software Integration and Compatibility	Connectivity with phones, apps, and computers – either via direct link or piggyback device connectivity.
Cost	Appropriate Cost	Find parts that exhibit good quality, but within reason, meet the needs and requirements only.
Inputs/Outputs	Measures Vital Signs	Wireless monitor/sensor patches that communicate back to an accessory like wristband. Also has inbuilt sensors like accelerometers and pulse sensors.
	Good Battery Life	Good rechargeable battery, lasts days at a time. Simple wireless recharging or a durable port that won't gather debris.
	Seamless Wireless Communications	Local near field communications such as Bluetooth.
	Processes and analyses measured data	Needs to have appropriate amount of internal memory, storage and processing power so that basic analysis can be done locally, whilst in depth data analysis can be done through other servers.

Based on the concepts generated in *Table 6*, a device that is easily put on and worn, that is simple and easily manufactured and unobtrusive is required. The device will rely heavily on existing technologies, combing them into one device that can retrieve the data measured, do simple analysis and storage, and communicate it to other devices.

3.1 The Chosen Concept

Based on the process up to this point, a wristband device was chosen as the main concept, containing some basic processing power, a battery and a form of wireless technology that can not only receive information from wireless sensors, but also communicate with other computing platforms, such as a smartphone device or a computer. This can then communicate the data to doctors and healthcare professionals via a secure network, alerting doctors to any notable relationships and providing them with the information to improve treatment and patient lifestyle.

3.2 Functional Flow – How Will the Functions Work?

To outline some primary and secondary functionality of this chosen concept, some functional flow block diagrams have been generated, showing the systematic processes followed by the device in particular stages.

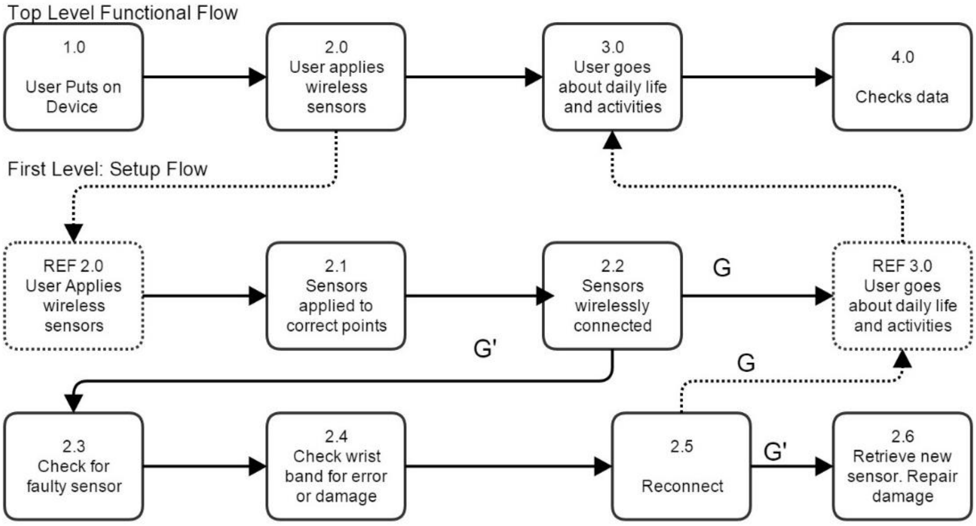

Figure 2: Functional Flow Top Level and Setup Flow

Figure 2 shows the top level function of the system, and below, the first level functions of the sensor application and connection to the device. The diagram is very simple to follow with some basic troubleshooting options (G and G'). *Figure 3* furthers this, again showing the top level functional flow of the device and then illustrating the possible flows of checking data in the system.

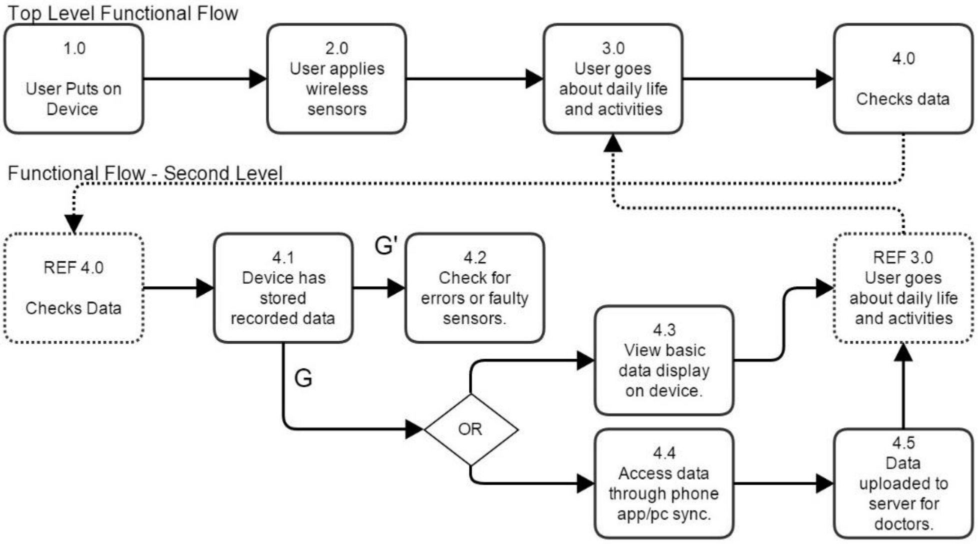

Figure 3: Functional Flow Second Level

As seen in *Figure 3*, assuming the device has correctly collected data from the sensors, it is aimed to have a few options for accessing the data. Ideally the current levels of each sensor can be accessed through a small interface on the device, but more detailed information of the levels, including graphs and analysis could be accessed through an app (either computer or smartphone app). When the data is accessed by the external computing device, the information is uploaded to an online server (assuming internet connection), where more advanced algorithms can sort through the data and identify trends and interactions that may be useful.

3.3 Concept Discussion

These flow diagrams could be altered, however, depending on the situation and the specific application of the device. The scope of this report aims primarily to create the device that interacts with the sensors and communicates them in a useful way. This could be adjusted depending on the scenario.

For example, the device could be fitted with Wi-Fi functionality, and emergency departments could assign bands to each patient with a variety of patches based on their symptoms, keeping all the logged patients monitored on a local network in the waiting room. Intelligent triage assignment and emergency allocations could be made based on the vital information being received from each patient, ensuring the people in the most need are attended to first. Likewise, if a person waiting in the emergency department goes into cardiac arrest, alarm bells would notify doctors exactly which person needs immediate attention.

Another conceptual application could include a use case for emergency accident scenes. Paramedics arriving to the scene of an accident, immediately assigning the wristband and necessary wireless monitor patches to the patients. The device could be fitted with cellular capabilities, communicating both location and vital signs back to the hospital they are being sent to such that doctors know what to expect for each patient.

For the design of this report, the wristband will be conceptually fitted with Bluetooth and Wi-Fi capabilities, being able to piggyback data usage and internet connection through an external device such as a mobile phone. The scope will remain limited to patients living with medical conditions from home, retrieving and sending data to a server doctors can keep track of.

4.0 Subsystem Definitions and Integration

The functions of this monitoring system can be assigned into different subsystems. These systems are the communications system, the user interface system, the data processing system, and the online server system. To understand what features come under which system and how they interact, functional allocation and systems interfacing have been utilized. *Figure 4* below outlines the subsystem partitions in an allocation map.

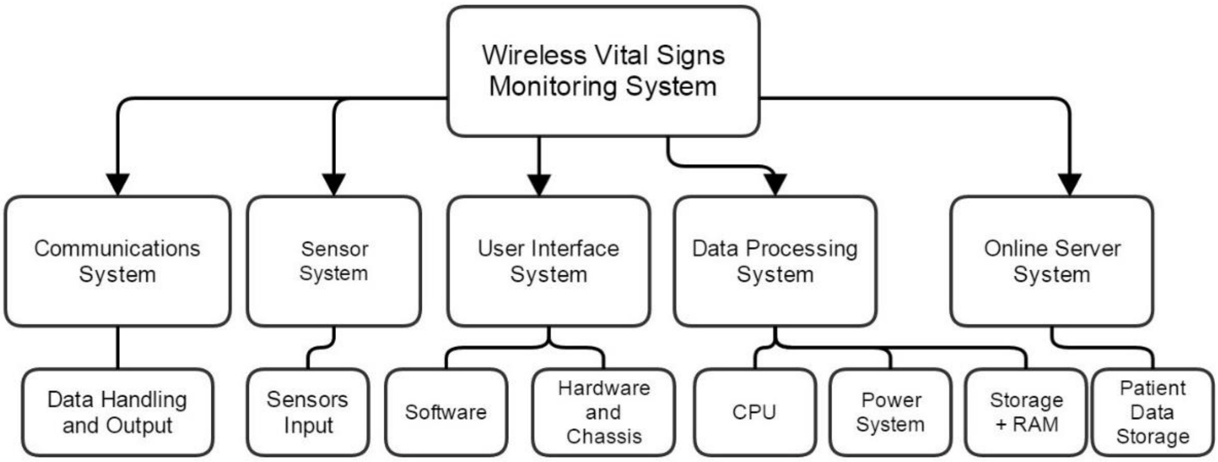

Figure 4: Subsystem Definitions

4.1 System Interactions (FBD)

With the different systems and subsystems defined in *Figure 4*, an FBD was generated to show relationships and interactions. *Figure 5* shows the Wireless Vital Signs monitoring system and in it, the interactions of the different subsystems. These essentially define the inner working of the system, showing that major important features include a communications system that receives measured information from the sensors subsystems, a user interface to display basic information back to the user, a separate user interface/software that can communicate with the device, providing greater depth data presentation and an internet source to update the online server system. These are all vital features and interactions for the customer requirements to be met and for the intended functionality to be possible.

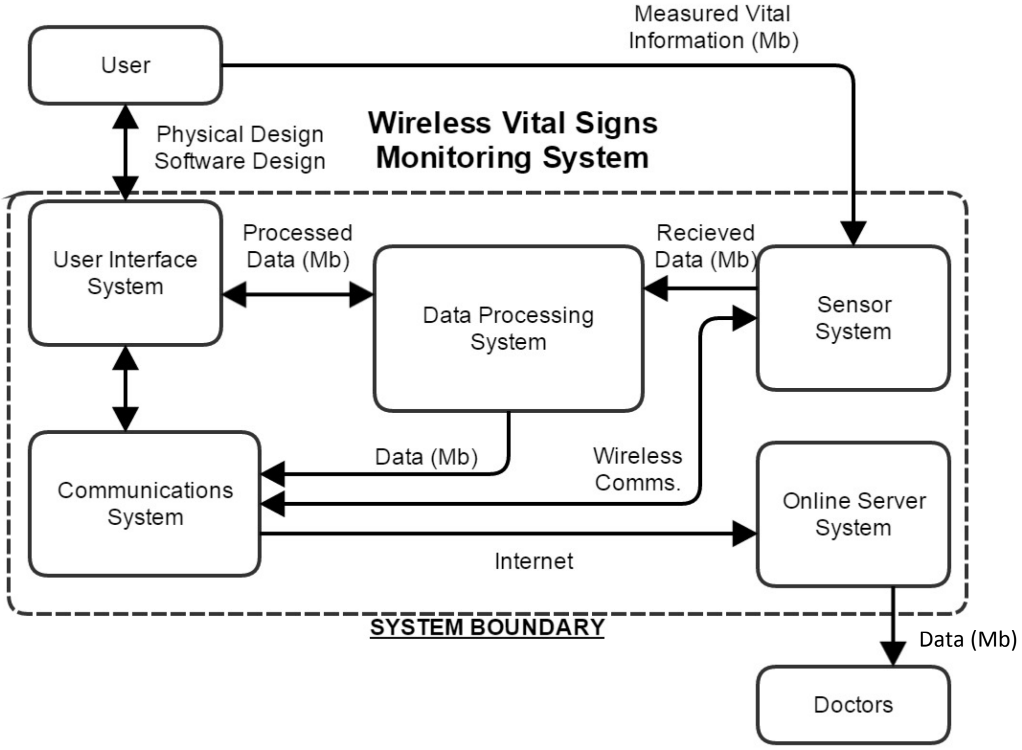

Figure 5: System interactions FBD

4.2 Which System is Most Important and What Does that Mean?

The difficulty in a complex system is ensuring the correct importance is assigned to each system and that the final product highlights this importance. By mapping each subsystems link to the initial customer requirements through the system attributes, the importance of each subsystem and the role it plays in meeting those requirements becomes apparent (*SlalomTech 2009*). *Table 7* demonstrates the links of each subsystem back to the initial requirements.

Considering the first most important requirement, the inputs and outputs, we can observe in *Table 7*, attributes A6.0 have high link with the communications system and the user interface system. This indicates that further investigation into these subsystems and their importance in the final design should be investigated further. Likewise, considering the second and third highest importance requirements, the comfort and durability, we see a high correlation between the user interface system and also the sensor system.

The user interface (both physical and software), the communications and the sensor subsystems are integral to meeting the customer requirements and the attributes associated with them (as highlighted in *Table 7),* and therefore, design focus must assign these subsystems the highest priorities.

Table 7: Attributes Cascade

Primary Attribute	Secondary Attribute	Tertiary Attribute	Related Subsystem
A1.0 Durability	A1.1 Waterproof	A1.1.1 Water & Dust Resistance	UI./SENS.
	A1.2 Tough	A1.2.1Impact Resistance	UI./SENS.
	A1.3 Long Product Life	A1.3.1 Material Life	UI./SENS.
		A1.3.2 MTBF	UI./SENS.
A2.0 Aesthetics	A2.1 Multiple Customization Options	A2.1.1 Color Options	UI.
		A2.1.2 Design Options	UI.
A3.0 Comfort	A3.1 Wearability	A3.1.1 Size Adjustability	UI.
		A3.1.2 Dimensions	UI.
		A3.1.3 Weight	UI./SENS./COMM./DATA.
A4.0 Ease of Use	A4.1 Customer Input Options	A4.1.1 User Inputs	UI.
	A4.2 Software Integration/Compatibility	A4.2.1 # Platform Compatibilities	UI./COMM./DATA.
A5.0 Cost	A5.1 Appropriate Cost	A5.1.1 Overall Cost	ALL
A6.0 Inputs/Outputs	A6.1 Measures Vital Signs	A6.1.1 Sensor Measurement Accuracy	SENS./COMM.
		A6.1.2 Sensory Variety/Types	SENS.
	A6.2 Good Battery Life	A6.2.1 Battery Capacity	DATA./COMM.
		A6.2.2 Battery Lifespan	DATA.
	A6.3 Seamless Wireless Communications	A6.3.1 Type of wireless Communication	COMMS./SENS.
		A6.3.1 Range of Wireless	COMMS./SENS.
		A6.3.2 # of Devices and Sensors	COMMS./SENS./DATA.
		A6.3.3 Server/Cloud Updates	COMMS./SERV.
	A6.4 Processes and Analyses Data	A6.4.1 Processing Speed	DATA.
		A6.4.2 Accuracy of Analysis Techniques	SENS./COMM./DATA.
		A6.4.3 Data Output Options	COMM./DATA./UI.

4.3 The Sensor System

Research into wireless medical monitors indicates that this subsystem may be able to be outsourced, as other researchers and companies are designing adhesive patches that can monitor vital information. One particular example of this is from research at the Oregon State University, where electrical engineers have developed a new sensor type where the components that were once bulky have been combining into one microchip, allowing the sensors to be roughly the size and thickness of a postage stamp. Their research indicates that these disposable and powerful sensors could easily be manufactured in high volumes at very low cost. *(Iran Daily, 2012)* Similarly, application of internal monitors could also be considered, with some companies investigating small ingestible sensors and implantable monitors. *Figure 6* highlights different categories of vital signs that could be measured, and the types of sensors that could be developed in collaboration with the companies already researching these.

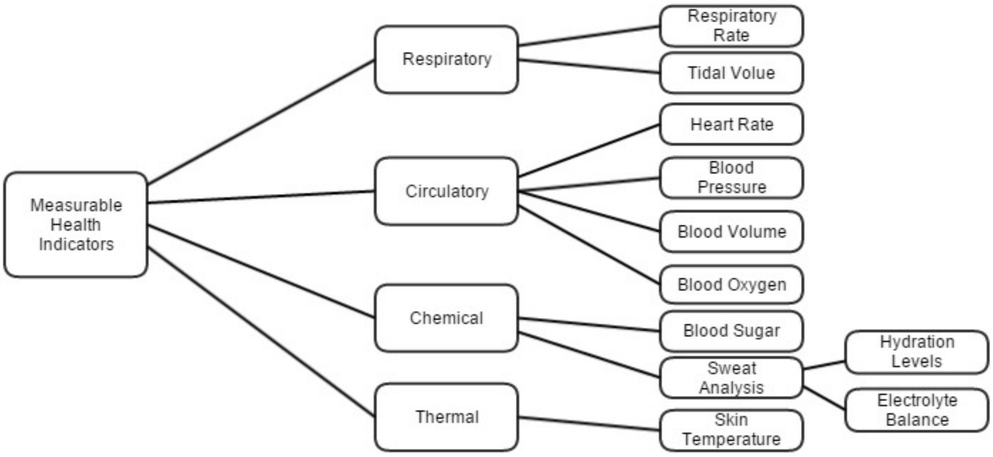

Figure 6: Concept Tree showing categories of vital signs that could be measured

4.4 The Communications System

The communications system is responsible for the interactions that take place between the sensors and the wristband, and likewise, the wristband and its external software (ie. Phone app). It will facilitate the pathways of data measured by the sensors through to the wristband to be stored, where it can be later uploaded to the online server through the internet connection of another device. Several considerations need to be taken into account when designing the wireless system and hence we must define some criteria for it. The chosen system must have an appropriately low power output and consumption, low cost and good data transfer rates. A comparison of some short range wireless technologies and their appropriateness to the system is seen in *Table 8* below.

Table 8: General Comparison of Communication Types) (Mensen, 2004) (Pulipati & Srnivas 2013)

Requirement	**NFC**	**Bluetooth V3**	**UWB**	**Wi-Fi (802.11g)**
Range	0.1m	Up to 100m	Up to 20m	30m
Power	Low	Low	Low	High
Data Rate	Up to 0.424 Mb/s	24 Mb/s	50-100 Mb/s	54 Mb/s
Cost	Low	Low	Low	High

Table 8 highlights that Wi-Fi is not a viable option as it is both expensive and high power, whereas NFC, Bluetooth and UWB (ultra wide band) are all lower power and lower cost. Wi-Fi will be eliminated from consideration (*Memsen 2004*). Further research into Ultra Wide Band communication indicates that it is still in research phases and therefore will not be adopted for this project (*Memsen 2004*). Bluetooth stands out with an effective range, good data transfer rates and low power. Whilst NFC appears lacking in range and data transfer rates, NFC is a complementary technology, capable of initiating other wireless connections (*Pulipati & Srnivas 2013)*

The communications system will adopt both NFC and Bluetooth; this will allow NFC to be used for initiating Bluetooth connections with the sensors with minimal effort.

4.5 The User Experience and Interface

The user interface plays a major role as a subsystem within this device, encompassing both the physical chassis and the associated software within the device and its external communications. A concept generation tree has been utilized in order to formulate ideas and outline the intended specifics of the user interface that may provide both an easy to use and comfortable experience. The design ideas outlined in *Figure 7 (next page)* will likely influence the final design of the wristband, impacting the prototype modelling, the production analysis and hence the lifecycle of the product.

Other necessary considerations into the user interface system are its intelligent features and warning systems that are able to alert the patient, their doctor and other people of possible danger. This could be warning signs such as rapid pulse, or high blood pressure, or low blood sugar for example. If these vital signs are recognised as major health and treatment indicators for the patient, the user interface system should have the ability to provide warning feedback through noise or vibration, and even possibly dial for emergency assistance if the patient needs urgent treatment. These are all considerations that should be taken into account, tested and integrated into the final design of the system.

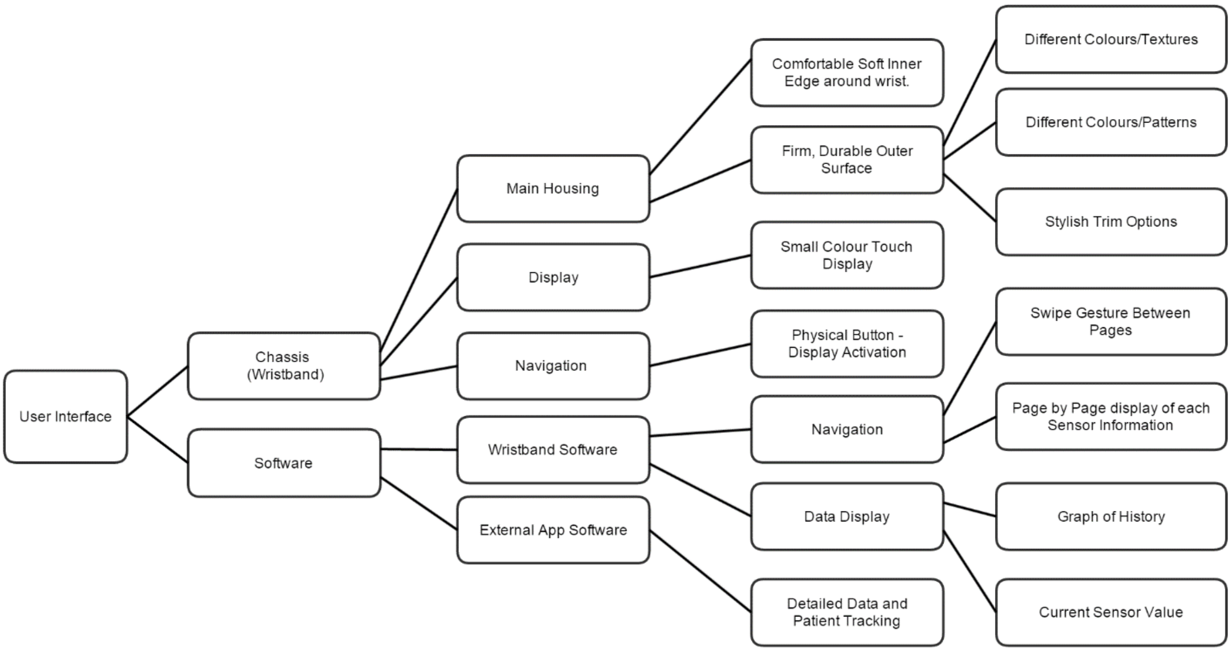

Figure 7: User Interface Concept Tree

5.0 Lifecycle Analysis

The lifecycle analysis aims to consider not only the production of the product, but also look at its technical use time and the products retirement. In doing so, the product may be made in such a way that not only reduces the inputs required for its creation, but diminishes the impact its life and end of life will have on the environment. By looking at the different phases of the lifecycle for this product, we are able to make decisions about how resources may be best utilized and in some cases, how those resources may be reused in other products.

5.1 Production

The manufacturing of this device will rely heavily on its final design and the materials required for it. As previously stated, the manufacturing process of the sensors has been verified as efficient and simple enough to produce large quantities at low costs. This is indicative of the low input costs and material costs required to manufacture such a small and simple device.

The production of the wristband aims to require little resources, and as the product is only about the size of a watch, the materials required should be minimal. Having considered possible design features of the external chassis and the user interface, it has been determined that the main body of the band will consist of a firm but flexible plastic that has a surface coating of a softer material for comfort. The screen and sensors will be set in this plastic housing. To have a completely recyclable body, two different recyclable materials will be utilized. The firm, flexible outer housing will be manufactured from a recycled PET (polyethylene terephthalate or RPET) as it has several advantages comparatively with other recycled plastics when it comes to energy consumption, environmental impact and low water consumption during (*de Souza 2015).* In addition to this, recent studies done by Pacific Research Consulting *(2004)* has outlined new recycling and forming processes that improves the quality of the recycled materials giving it good strength and impact resistance. This tougher plastic will then be combined with a softer recycled silicone elastomer inner surface, not only reducing manufacturing and production footprints, but providing a more comfortable wear, excellent chemical resistance, stain resistance, thermal resistance and hydrophobic properties. (*Rapra 2013*) By consciously and carefully selecting recyclable materials that are suitable for its use, the production phase aims to reduce the environmental impact of this product.

5.2 Operation and End of Life

The operation impact of this device requires power input to charge the wristband and the supply of the adhesive sensors. Whilst the research by Oregon State University (*Iran Daily, 2012*) has not specified the product life of the sensors they have created, ideally, they would be made as rechargeable patches with replaceable adhesive strips. This highlights possibilities of waste production within the products use, and hence this should aim to be optimized. This could be done by determining the amount of adhesive material needed to most effectively attach the sensor to the patient. In addition to this analysis, by delivering these adhesive patches in low waste packaging that have an sensibly large quantities per box will reduce the impact of the packaging waste and the transportation. As the product is made of recyclable materials it can simply become the inputs for another system requiring these recycled materials.

5.3 Design Models

Whilst the main design of the wristband and the associated system has relied heavily upon the Vee diagram for its process with the addition and rearrangement of some tools, the system's software design needs to be a highly accurate and robust system. The software development process (which would be an added process of its own) would likely rely upon the spiral model, which boasts its benefits in early prototyping and testing that is well documented. (*Munassar, 2010)*

As this is a medical device, it is imperative that the software has been fully completed and working in every aspect, however, if there happened to be bugs and issues with the software, the spiral process can continue with updates and further prototyping and testing of new code to bring improvements and fixes. This would also be applicable to the external software app, as regular updating could continually bring improvements to the user interface and its usability.

6.0 Testing

Table 9 outlines some examples of tests that are proposed to evaluate the functions of the system against the customer requirements. Doing so verifies the systems validity and usefulness as a solution; checking that it not only solves the problem but solves it correctly is essential! The tests defined below include the type and level of test it is, the attribute it is testing and a brief outline of what the test aims to achieve, and thus verify.

Table 9: Proposed Testing

Attribute	**Proposed Testing Method**
A1.1 Waterproof	*Prototype/Operational Testing (Type II and III)* *Test Person: Technician/Certified Test Facility Operator* *Pass Rate: Benchmark variance <±10%* *Metric: IPxx Rating* 1. Initial prototypes testing against their waterproof/dustproof IPxx Rating. 2. Operational testing continues, testing 10 or more operational models; no more than 10% variance in the given rating must be present.
A1.2 Tough	*Prototype/Operational Testing (Type II and III)* *Test Person: Technician/Certified Test Facility Operator* *Pass Rate: Benchmark variance <±10%*

	Metric: IPk Rating 1. Initial chassis prototypes tested against the toughness and impact resistance. 2. Operational models, testing 10 or more operational models; no more than 10% variance in the given rating must be present.
A1.3 Long Product Life & A5.1 Appropriate Cost	*Analytical Models/Proof of Concept (Type I)* *Test Person: Engineer/Material Specialist* *Pass Rate: Benchmark ±10%* *Metric: Years* 1. Analysis of all the materials present within the product, including their theoretical lifespan and costs. 2. Comparison against actual experimental lifespans (from research). 3. Conclude with bill of materials and estimated manufacturing costs.
A3.1 Wearability	*Prototype/Operational Testing (Type II and III)* *Test Person: Survey Participants* *Pass Rate: Benchmark >90% Satisfaction Rating* *Metric: ~* 1. Construct suitable prototypes, allow test group to try the product and give anonymous rating of its wearability (comfort etc.) 2. Conduct larger scale survey with operational models.
A6.1 Measures Vital Signs	*Proof of Concept (Type I)* *Test Person: Engineer/Medical Specialist* *Pass Rate: >95% accuracy over test period* *Metric: %* 1. Using breadboard models, adhesive sensors and existing medical equipment, compare the accuracy of the new system against the existing, non-portable measurement methods and equipment.
A6.2 Good Battery Life	*Analytical Models/Proof of Concept (Type I)* *Test Person: Engineer/Technician* *Pass Rate: > Minimum Benchmark* *Metric: Days/Hours/Mins + mA/hrs* 1. Constructing an analytical model of the electronics, in addition to necessary software and conduct theoretical analysis of battery usage. 2. Compare with proof of concept model construction
A6.4 Processes and Analyses Data	Analytical Models/Proof of Concept (Type I) *Test Person: Engineer/Programmer* *Pass Rate: >95% accuracy* *Metric: %* 1. Write code for the system that handles the same data input. 2. Demonstrate usage of data types and useful representations.

By performing these proposed tests at the different phases of the testing process, the system can be verified against its initial customer and design requirements.

Conclusion & Next Steps

A systems engineering approach has been utilized throughout this portfolio to analyze and formulate a solution to the problem at hand. The proposed solution is encompassed in the wristband concept, having features that consider both the functional and user design requirements to provide a comfortable and effective outcome. The next step in this process includes further testing and analysis, with prototype construction and implementation strategy that would be formulated in partnership with doctors and their patients.

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